

SUPPORT DOCUMENTS

List of Support Documents

1. Formula and Certificate of Analysis for Solid Purified Diet
2. Analytical Method of Vinyl Chloride Monomer and Formaldehyde
3. Certificates of Analysis for Test Substance (Methanol)
4. Records on Operating Conditions of Long-Term Inhalation Study Facility (Inside the Inhalation Laboratory)
Daily Inspection Chart (Outside the Inhalation Laboratory)
5. A Records of Temperature and Humidity Inside the Exposure Chamber (One Example)
6. Details of Animal Care and Management
7. Results of Antibody Test on Pathogenic Microorganisms

Support Document 1: Formula and Certificate of Analysis for Solid Purified Diet*Received on 08/11/1983**August 11, 1983*

Mitsubishi Kasei Institute of Toxicology and Environmental Sciences

. *Dr. Matsuura**Funabashi Farms, Co., Ltd.
Tomo Watarai**For the purpose of the subject matter, reported below is formula of purified diet cp23 for F 344 rats.*

<i>Record</i>		
<i>Name of Raw Material</i>	<i>%</i>	<i>Remarks</i>
<i>Casein</i>	<i>26.7 %</i>	<i>New Zealand Dairy Board</i>
<i>Methionine</i>	<i>0.3</i>	<i>Takeda Science</i>
<i>Granulated sugar</i>	<i>10.0</i>	<i>Higashi Nihon Sugar Mfg.</i>
<i>Cornstarch</i>	<i>45.0</i>	<i>Kato Kagaku</i>
<i>Cellulose</i>	<i>7.0</i>	<i>Sanyo-Kokusaku Pulp</i>
<i>Refined soybean oil</i>	<i>5.0</i>	<i>Showa Sangyo</i>
<i>USP vitamins</i>	<i>1.0</i>	<i>Takeda Science</i>
<i>USP minerals</i>	<i>5.0</i>	<i>Takeda Science</i>
	<i>100.00</i>	

See attachment for Results of analysis.

USP Vitamins

Vitamin A	2000 IU
Vitamin D	200 IU
Vitamin E	10 IU
Menadione	0.5 mg/ 100 g
Choline	200 mg/ 100 g
Aminobenzoic acid	10 mg/ 100 g
Inositol	10 mg/ 100 g
Niacin	4 mg/ 100 g
Calcium pantothenate	4 mg/ 100 g
Riboflavin	0.8 mg/ 100 g
Thiamine hydrochloride	0.5 mg/ 100 g
Pyridoxine hydrochloride	0.5 mg/ 100 g
Folic acid	0.2 mg/ 100 g
Biotin	0.04 mg/ 100 g
Vitamin B12	0.003 mg/ 100 g
Base material:	Cornstarch

USP Minerals

Potassium phosphate	389 g/ 1 kg
Anhydrous magnesium sulfate	57.3 g/ 1 kg
Calcium carbonate	381.4 g/ 1 kg
Ferric sulfate.7H ₂ O	27.0 g/ 1 kg
Manganese sulfate.H ₂ O	4.01 g/ 1 kg
Zinc sulfate.7H ₂ O	0.548 g/ 1 kg
Copper sulfate.5H ₂ O	0.477 g/ 1 kg
Cobalt chloride.6H ₂ O	0.023 g/ 1 kg
Sodium chloride	139.3 g/ 1 kg
Potassium iodide	0.79 g/ 1 kg
Base material:	Cornstarch

Issue No. 16071343-002

August 3, 1983

CERTIFICATE OF ANALYSIS

Requester: Funabashi Farms, Co., Ltd.

Name of Specimen Purified diet for rats
or Sample:Notes: Manufactured on July 21, 1983
 Lot No. 344

The following are the results of analysis on the abovementioned specimen submitted to our center on July 25, 1983.

Japan Food Research Laboratories
52-1 Motoyoyogi-cho, Shibuya-ku, Tokyo
Branch: 3-1 Toyotsu-cho, Suita-shi, Osaka
[seal: Seal of Japan Food Research Laboratories]

RESULTS OF ANALYSIS

Subject of Analysis	Result	Detection Limit	Note	Analytical Method
Moisture content	7.2 %			Heated-air drying method under normal atmospheric pressure (2 hours at 135 °C)
Crude protein	23.8 %		1	Kjeldahl method
Crude fat	5.0 %			Soxhlet extraction
Crude fiber	4.6 %			Filtering
Crude ash	4.5 %			Direct ashing method

Note 1: 6.25 nitrogen-to-protein conversion factor was used.

End of report

Please obtain the center's approval when publishing the certificate of analysis.

Support Document 2: Analytical Method of Vinyl Chloride Monomer and Formaldehyde

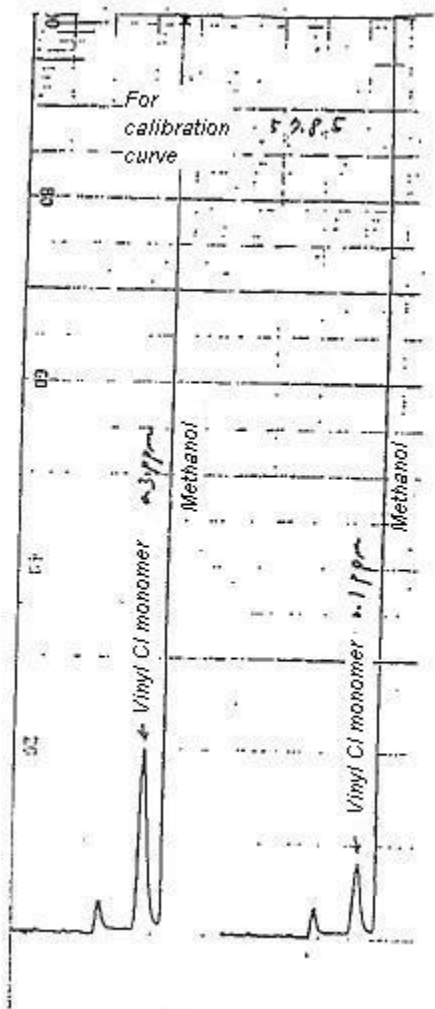
The method used in the food hygiene test was adopted to analyze vinyl chloride monomer in methanol. ("Handling of Containers and Packaging Made of Vinyl Chloride Resin," Environmental Health and Food Chemistry Bulletin No. 53, Notification from the Director of Environmental Health Bureau, Ministry of Health and Welfare, December 23, 1975).

As for analysis of formaldehyde within methanol, a method to calculate formalin based on oxygen consumption of potassium permanganate was utilized since a proper detector that can identify formalin level of about 3 ppm does not exist.

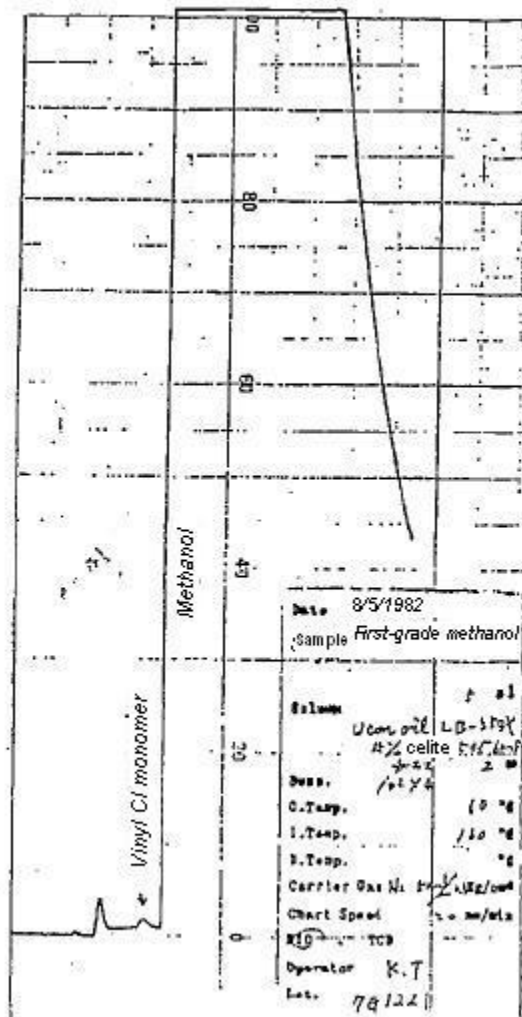
A sample of analytical determination (standard substance for calibration curve as well as sample) of vinyl chloride monomer in methanol is shown below.

Standard Solution

(Vinyl chloride monomer/ methanol)



Sample (first-grade methanol)



A. Analytical Method of Monomer in Food Packaging and Container Materials

Taro Okada

1. Vinyl chloride monomer

(1) Analysis of VCl monomer in resin

Environmental Health
and Food Chemistry
Bulletin No. 53
December 23, 1975

Dear prefectural governors,
mayors of ordinance-
designated cities, and
directors of special wards,

Director of Environmental
Health Bureau, Ministry of
Health and Welfare

Handling of Containers and Packaging Made of Vinyl Chloride Resin (Notification)

The quality of vinyl chloride resin food containers and packaging (hereafter, "VCl containers and packaging") has been controlled by Standards for Heavy Metals and Other Substances (Notice No. 178, Ministry of Health and Welfare, June 1973). Recently, however, some studies revealed that vinyl chloride monomer (hereafter, "VCM") remains within resin and migrates into food if high level of residue is present. For this reason, traders concerned have been instructed to manufacture high quality VCl containers and packaging, and at the same time, National Institute of Health Sciences has been conducting research on migration and so forth of VCM into food.

Based on the studies conducted thus far, the residual limit of VCM within materials without a risk of VCM migration into food as well as appropriate test methods were obtained. Please use the following information to guide traders concerned for the time being.

In case you are not aware, manufacturers of VCl containers and packaging have been, since the end of last year, producing and distributing products having no risk of VCM migration into food. Furthermore,

as of October 15 of this year, they have set the limit of residual level of VCM as 1 ppm or less, as a voluntary standard. Materials for all the VCl containers and packaging for sale have been tested, and if any pre-existing VCl containers and packaging do not meet the voluntary standard, they are taking steps to recall the product(s).

NOTE

1. From now on, all VCl containers and packaging to be manufactured and sold as well as to be used by food manufacturers must pass the attached test.
2. In the immediate future, focus guidance on VCl containers and packaging to be used with the following food:
Soy sauce, sauce, vinegar, cooking oil, sweet rice wine for cooking and margarine

Test Method for VCl Containers and Packaging

a. Preparation of Test Solution

Shred sample to less than 5 mm width, precisely measure about 1 g of the shredded sample, and place it in a 20 ml volumetric flask. Add appropriate amount of tetrahydrofuran to the flask, leave it in a cool location and shake occasionally. After the sample has resolved, add tetrahydrofuran to obtain exactly 20 ml of test solution.

Add either ferrous sulfate or lithium aluminum hydrate to tetrahydrofuran for distillation, and make sure no substance that may interfere with the test is present.

b. Test

☐ Qualitative Test

Take 10 μ l each of test solution and vinyl chloride standard solution, and perform gas chromatography in operating conditions below. Then, compare detection times of the peak in gas chromatogram of the test solution and the peak of vinyl chloride in gas chromatogram of the vinyl chloride standard solution.

OPERATING CONDITION 1

Column carrier: Use kieselguhr (standard wire sieve 149-177 μ) for gas chromatography.

Column filler: Add Ucon oil LB-550 X in the amount equivalent to 15-20 % of the column carrier.

Column: Use 3-4 mm diameter, 2,000-3,000 mm long stainless tube or glass tube.

Column temperature: 60-70 °C

Test solution inlet temperature: 150 °C

Detector: Use a hydrogen flame ionization detector. Operate at around 200 °C. Adjust the level of hydrogen and air so that the detection sensitivity is at maximum.

Carrier gas: Use nitrogen gas. Adjust the flow rate so that a steady stream of vinyl chloride would appear in about 90 seconds.

OPERATING CONDITION 2

Column filler: Use Chromasolv 104 (standard wire sieve 149-177 μ).

Column: Use 3-4 mm diameter, 1,500 mm long stainless tube or glass tube.

Column temperature: 120 °C

Test solution inlet temperature: 150 °C

Detector: Use a hydrogen flame ionization

detector. Operate at around 150 °C. Adjust the level of hydrogen and air so that the detection sensitivity is at maximum.

Carrier gas: Use nitrogen gas. Adjust the flow rate so that vinyl chloride would flow out in about 3-4 minutes.

□ Quantitative Test

- 1) If the detection times of the peak in gas chromatogram of the test solution and the peak of vinyl chloride in gas chromatogram of the vinyl chloride standard solution match in the qualitative test, perform the following tests.
- 2) When measuring the peak area of vinyl chloride in test solution based on the results of test performed under the operating condition 1 or 2, whichever is appropriate, the area cannot be greater than the peak area of vinyl chloride standard solution.

Vinyl chloride standard solution 1:

Assemble 1-liter standard vacuum bottle for gas collection as shown in the figure. Switch the three-way stopcock to the vacuum pump and vacuumize inside the collection bottle. When the mercury manometer becomes stationary to indicate completion of vacuumization inside the bottle, switch the three-way stopcock to the vinyl chloride cylinder and gradually send vinyl chloride into the bottle. When the mercury manometer returns to 1 atmosphere, stop the valve on the cylinder and switch the three-way stopcock to re-vacuumize the bottle.

Repeat this process three times, and at the end of last cycle, stop the cylinder when the mercury manometer indicates slightly higher pressure than 1 atmosphere. Tighten the fluororesin valve and remove the three-way stopcock and stainless needle to complete collection of vinyl chloride.

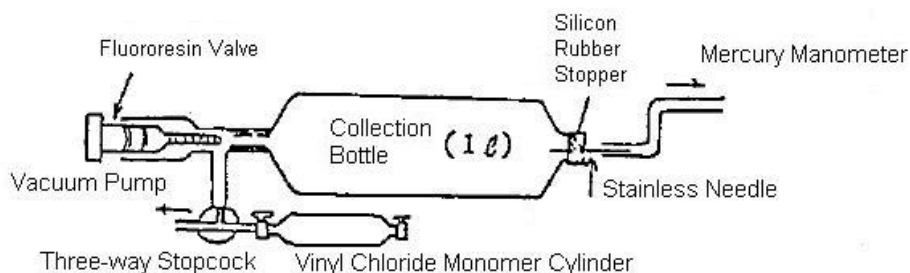


Fig. 1

Separately, pour 20 ml of ethyl alcohol in a 200 ml test tube equipped with a serum cap or silicon rubber, and cool it with methyl alcohol and dry ice in advance.

Next, using a 50 μ l micro syringe, collect 8 μ l of vinyl chloride through silicon rubber stopper of the collection bottle in the figure. Gradually inject the vinyl chloride in 20 ml of pre-cooled ethyl alcohol, dissolve it and shake the tube well to obtain even solution. Then, take 1 ml of the solution and add cooled ethyl alcohol to obtain exactly 20 ml of solution.

Ethyl alcohol: Add ferrous sulfate for distillation and make sure no substance that may interfere with the test is present.

1-liter standard vacuum bottle for gas collection: One that is described in "Test Methods for Malodorous Substances," Environmental Agency Notification No. 9, May 30, 1972.

c. Additional Remarks

Aluminum lithium hydrate: Japanese Industrial Standards Special Grade Chemicals

All other reagents without special mention follow Standards for Food and Additives (Notification No. 370, Ministry of Health and Welfare, 1959).

(2) Analysis of VCM in Foods

(Japan Hygienic PVC Association)

Either dissolve or suspend food in proper solvent (ethanol or acetone. For margarine, THF is suitable), and while heating in hot-water bath, either expel VCM by nitrogen gas (nitrogen expulsion method) or distil it (distillation method). Collect VCM in trap tube filled with ethanol pre-cooled in refrigerant. Measure this ethanol solution with gas chromatograph equipped with a hydrogen flame ionization detector.

The detection limit of VCM using this pre-treatment method is 0.05 ppm (W/ W).

Details of nitrogen expulsion method and distillation method are as follows:

1) Nitrogen Expulsion Method

Set the temperature of water bath to 60-80 °C. Then, take 10 ml of ethanol with a ball pipette and put it in the VCM trap tube. Set it by soaking in a dry ice/ ethanol bath

Put 20 ml of solvent in an impinger, weigh out 10 g of sample and mix it with the solvent. Then, quickly load the impinger to the system, adjust the nitrogen gas flow rate to 60 ml/ min. and soak in the hot-water bath.

After running nitrogen gas for 30-60 minutes, remove the VCM trap tube from the system, and put the silicon rubber stopper. Store it while soaking in the dry ice/ ethanol bath and submit it to gas chromatography.

If the sample is solid, not completely dissolved... [page missing]

Support Document 3: Certificates of Analysis for Test Substance (Methanol)

COPY

Governmental Commission Methanol	Certificate of Analysis	No. 07041		
TO:		August 10, 1982		
Delivery No. 2 (lot delivered on 8/9)		Testers	[seal: Uyama]	[seal: Tokuno]
Specimen:	Methanol (Methyl Alcohol)	Test Grade:	Pure Grade 1 grade	
Test Date:	August 4, 1982	Climate:	Weather:	Temp: °C
Date of Mfg.:		Quantity:	14 kg x 10	
Lot No.:	7H1102	Remarks:		
Items	Standards	Assay Value		
Solubility in water	To pass test	Pass		
Water	Max. 0.3 %	0.017 %		
Non-volatile matter	Max. 0.003 %	trace		
Acid (as HCOOH)	Max. 0.004 %	0.00027 %		
Alkali (as NH ₃)	Max. 0.0005 %	trace		
Acetone, aldehyde (as CH ₃ COH ₃)	Max. 0.005 %	0.001%		
Ethyl alcohol	To pass test	pass		
Substances reducing permanganate	Max. 0.0015 %	pass		
Substances darkened by H ₂ SO ₄	To pass test	pass		
Boiling range (64-66 °C)	Min. 95 v/v %	pass		
ASSAY (by specific gravity)	Min. 99.6 v/v %	99.9 %		
Specific gravity (20/ 20 °C)	Max. 0.794	0.7930		
* Vinyl chloride	Max. 1 ppm	About 0.015 ppm		
* Formaldehyde	Max. 3 ppm	About 2.5 ppm or less		
DECISION	PASSED 7H1102	[seal: Seal of Junsei Chemical Co., Ltd. Saitama Plant] 1-6 Ohmanochō, Koshigaya-shi, Saitama, Testing Division, Saitama Plant, Junsei Chemical Co., Ltd. TEL: Koshigaya (62) 6161		

COPY

Governmental Commission Methanol	Certificate of Analysis	No. 07276 [seal: Takeda, 9/30/82, (Kazu)]		
TO:		September 29, 1982		
Delivery No. 3(9/30)		Testers	[seal: Uyama]	[seal: Tokuno]
Specimen:	Methanol (Methyl Alcohol)	Test Grade:	Pure Grade 1 grade	
Test Date:	Sept. 20, 1982	Climate:	Weather:	Temp: °C
Date of Mfg.:		Quantity:	14 kg x 10	
Lot No.:	7I1396	Remarks:		
Items	Standards	Assay Value		
Solubility in water	To pass test	Pass		
Water	Max. 0.3 %	0.018 %		
Non-volatile matter	Max. 0.003 %	trace		
Acid (as HCOOH)	Max. 0.004 %	0.00025 %		
Alkali (as NH ₃)	Max. 0.0005 %	trace		
Acetone, aldehyde (as CH ₃ COH ₃)	Max. 0.005 %	0.001%		
Ethyl alcohol	To pass test	pass		
Substances reducing permanganate	Max. 0.0015 %	pass		
Substances darkened by H ₂ SO ₄	To pass test	pass		
Boiling range (64-66 °C)	Min. 95 v/v %	pass		
ASSAY (by specific gravity)	Min. 99.6 v/v %	99.9 %		
Specific gravity (20/ 20 °C)	Max. 0.794	0.7930		
* Vinyl chloride	Max. 1 ppm	About 0.015 ppm		
* Formaldehyde	Max. 3 ppm	About 2.5 ppm or less		
DECISION	PASSED 7I1396 7I1396	[seal: Seal of Junsei Chemical Co., Ltd. Saitama Plant] 1-6 Ohmanochō, Koshigaya-shi, Saitama, Testing Division, Saitama Plant, Junsei Chemical Co., Ltd. TEL: Koshigaya (62) 6161		

COPY

Governmental Commission Methanol	Certificate of Analysis		No. 07587	
	TO: _____		November 4, 1982	
Delivery No.4		[seal: Takeda, 11/5/82, (Kazu)]	Testers	[seal: Uyama]
				[seal: Tokuno]
Specimen:	Methanol (Methyl Alcohol)	Test Grade:	Pure Grade 1 grade	
Test Date:	October 30, 1982	Climate:	Weather:	Temp: °C
Date of Mfg.:		Quantity:	14 kg x 20	
Lot No.:	7K1076	Remarks:		
Items		Standards	Assay Value	
Solubility in water		To pass test	Pass	
Water		Max. 0.3 %	0.014 %	
Non-volatile matter		Max. 0.003 %	trace	
Acid (as HCOOH)		Max. 0.004 %	0.00067 %	
Alkali (as NH ₃)		Max. 0.0005 %	trace	
Acetone, aldehyde (as CH ₃ COH ₃)		Max. 0.005 %	0.001%	
Ethyl alcohol		To pass test	pass	
Substances reducing permanganate		Max. 0.0015 %	pass	
Substances darkened by H ₂ SO ₄		To pass test	pass	
Boiling range (64-66 °C)		Min. 95 v/v %	pass	
ASSAY (by specific gravity)		Min. 99.6 v/v %	99.9 %	
Specific gravity (20/ 20 °C)		Max. 0.794	0.7930	
* Vinyl chloride		Max. 1 ppm	About 0.015 ppm	
* Formaldehyde		Max. 3 ppm	About 2.5 ppm or less	
DECISION	PASSED	[seal: Seal of Junsei Chemical Co., Ltd. Saitama Plant] 1-6 Ohmanochi, Koshigaya-shi, Saitama, Testing Division, Saitama Plant, Junsei Chemical Co., Ltd. TEL: Koshigaya (62) 6161		

COPY

Governmental Commission Methanol	Certificate of Analysis		No. 02205	
	TO: _____		January 18, 1983	
Delivery No. 5		[seal: Takeda, 1/18/83, (Kazu)]	Testers	[seal: Uyama]
				[seal: Tokuno]
Specimen:	Methanol (Methyl Alcohol)	Test Grade:	Pure Grade 1 grade	
Test Date:	January 18, 1983	Climate:	Weather:	Temp: °C
Date of Mfg.:		Quantity:	14 kg x 10	
Lot No.:	8A1252	Remarks:		
Items		Standards	Assay Value	
Solubility in water		To pass test	Pass	
Water		Max. 0.3 %	0.015 %	
Non-volatile matter		Max. 0.003 %	trace	
Acid (as HCOOH)		Max. 0.004 %	0.0008 %	
Alkali (as NH ₃)		Max. 0.0005 %	trace	
Acetone, aldehyde (as CH ₃ COH ₃)		Max. 0.005 %	0.001%	
Ethyl alcohol		To pass test	pass	
Substances reducing permanganate		Max. 0.0015 %	pass	
Substances darkened by H ₂ SO ₄		To pass test	pass	
Boiling range (64-66 °C)		Min. 95 v/v %	pass	
ASSAY (by specific gravity)		Min. 99.6 v/v %	99.9 %	
Specific gravity (20/ 20 °C)		Max. 0.794	0.7930	
* Vinyl chloride		Max. 1 ppm	About 0.13 ppm	
* Formaldehyde		Max. 3 ppm	About 2.5 ppm or less	
DECISION	PASSED	[seal: Seal of Junsei Chemical Co., Ltd. Saitama Plant] 1-6 Ohmanochi, Koshigaya-shi, Saitama, Testing Division, Saitama Plant, Junsei Chemical Co., Ltd. TEL: Koshigaya (62) 6161		

COPY

Governmental Commission Methanol	Certificate of Analysis		No. 02399	
[seal: Takeda, 2/22/83, (Kazu)]		TO:		
Delivery No.6		February 22, 1983		
Testers	[seal: Uyama]		[seal: Tokuno]	
Specimen:	Methanol (Methyl Alcohol)	Test Grade:	Pure Grade 1 grade	
Test Date:	February 21, 1983	Climate:	Weather:	Temp: °C
Date of Mfg.:		Quantity:	14 kg x	
Lot No.:	8B1187	Remarks:		
Items	Standards	Assay Value		
Solubility in water	To pass test	Pass		
Water	Max. 0.3 %	0.008 %		
Non-volatile matter	Max. 0.003 %	trace		
Acid (as HCOOH)	Max. 0.004 %	0.0004 %		
Alkali (as NH ₃)	Max. 0.0005 %	trace		
Acetone, aldehyde (as CH ₃ COH ₃)	Max. 0.005 %	0.001%		
Ethyl alcohol	To pass test	pass		
Substances reducing permanganate	Max. 0.0015 %	pass		
Substances darkened by H ₂ SO ₄	To pass test	pass		
Boiling range (64-66 °C)	Min. 95 v/v %	pass		
ASSAY (by specific gravity)	Min. 99.6 v/v %	99.9 %		
Specific gravity (20/ 20 °C)	Max. 0.794	0.7930		
* Vinyl chloride	Max. 1 ppm	About 0.022 ppm		
* Formaldehyde	Max. 3 ppm	About 2.5 ppm or less		
DECISION	PASSED	[seal: Seal of Junsei Chemical Co., Ltd. Saitama Plant] 1-6 Ohmanocho, Koshigaya-shi, Saitama, Testing Division, Saitama Plant, Junsei Chemical Co., Ltd. TEL: Koshigaya (62) 6161		

COPY

Governmental Commission Methanol	Certificate of Analysis		No. 08709	
[seal: Masaki, 5/13/83, (Kazu)]		TO: Mr. Takeda, Safety Institute		
Delivery No. 7		May 11, 1983		
Testers	[seal: Uyama]		[seal: Tokuno]	
Specimen:	Methanol (Methyl Alcohol)	Test Grade:	Pure Grade 1 grade	
Test Date:	April 14, 1983	Climate:	Weather:	Temp: °C
Date of Mfg.:		Quantity:	14 kg x 10	
Lot No.:	8B1357	Remarks:		
Items	Standards	Assay Value		
Solubility in water	To pass test	Pass		
Water	Max. 0.3 %	0.012 %		
Non-volatile matter	Max. 0.003 %	trace		
Acid (as HCOOH)	Max. 0.004 %	0.0003 %		
Alkali (as NH ₃)	Max. 0.0005 %	trace		
Acetone, aldehyde (as CH ₃ COH ₃)	Max. 0.005 %	0.001%		
Ethyl alcohol	To pass test	pass		
Substances reducing permanganate	Max. 0.0015 %	pass		
Substances darkened by H ₂ SO ₄	To pass test	pass		
Boiling range (64-66 °C)	Min. 95 v/v %	pass		
ASSAY (by specific gravity)	Min. 99.6 v/v %	99.9 %		
Specific gravity (20/ 20 °C)	Max. 0.794	0.7930		
DECISION	PASSED	[seal: Seal of Junsei Chemical Co., Ltd. Saitama Plant] 1-6 Ohmanocho, Koshigaya-shi, Saitama, Testing Division, Saitama Plant, Junsei Chemical Co., Ltd. TEL: Koshigaya (62) 6161		

COPY

Governmental Commission Methanol	<u>Certificate of Analysis</u>		No. 03026	
TO:		June 6, 1983		
Delivery No.8		Testers	[seal: Uyama]	[seal: Tokuno]
Specimen:	Methanol (Methyl Alcohol)	Test Grade:	Pure Grade 1 grade	
Test Date:	June 2, 1983	Climate:	Weather:	Temp: °C
Date of Mfg.:		Quantity:	14 kg x 10	
Lot No.:	8F1084	Remarks:		
Items		Standards	Assay Value	
Solubility in water		To pass test	Pass	
Water		Max. 0.3 %	0.012 %	
Non-volatile matter		Max. 0.003 %	trace	
Acid (as HCOOH)		Max. 0.004 %	0.0003 %	
Alkali (as NH ₃)		Max. 0.0005 %	trace	
Acetone, aldehyde (as CH ₃ COH ₃)		Max. 0.005 %	0.001%	
Ethyl alcohol		To pass test	pass	
Substances reducing permanganate		Max. 0.0015 %	pass	
Substances darkened by H ₂ SO ₄		To pass test	pass	
Boiling range (64-66 °C)		Min. 95 v/v %	pass	
ASSAY (by specific gravity)		Min. 99.6 v/v %	99.9 %	
Specific gravity (20/ 20 °C)		Max. 0.794	0.7930	
* Vinyl chloride		Max. 1 ppm	About 0.01 ppm	
* Formaldehyde		Max. 3 ppm	About 2.5 ppm or less	
DECISION	PASSED	[seal: Seal of Junsei Chemical Co., Ltd. Saitama Plant] 1-6 Ohmanocho, Koshigaya-shi, Saitama, Testing Division, Saitama Plant, Junsei Chemical Co., Ltd. TEL: Koshigaya (62) 6161		

COPY

Governmental Commission Methanol	ME 58	<u>Certificate of Analysis</u>		No. 03163	
TO: Mitsubishi Kasei Institute of Toxicology and Environmental Sciences, Ltd.		July 5, 1983			
Delivery No. 9		Testers	[seal: Uyama]	[seal: Tokuno]	
Specimen:	Methanol (Methyl Alcohol)	Test Grade:	Pure Grade 1 grade		
Test Date:	June 28, 1983	Climate:	Weather:	Temp: °C	
Date of Mfg.:		Quantity:	14 kg x 10		
Lot No.:	8F1687	Remarks:			
Items		Standards	Assay Value		
Solubility in water		To pass test	Pass		
Water		Max. 0.3 %	0.015 %		
Non-volatile matter		Max. 0.003 %	trace		
Acid (as HCOOH)		Max. 0.004 %	0.0003 %		
Alkali (as NH ₃)		Max. 0.0005 %	trace		
Acetone, aldehyde (as CH ₃ COH ₃)		Max. 0.005 %	0.001%		
Ethyl alcohol		To pass test	pass		
Substances reducing permanganate		Max. 0.0015 %	pass		
Substances darkened by H ₂ SO ₄		To pass test	pass		
Boiling range (64-66 °C)		Min. 95 v/v %	pass		
ASSAY (by specific gravity)		Min. 99.6 v/v %	99.9 %		
Specific gravity (20/ 20 °C)		Max. 0.794	0.7930		
* Vinyl chloride		Max. 1 ppm	About 0.02 ppm		
* Formaldehyde		Max. 3 ppm	About 2.5 ppm or less		
DECISION	PASSED	[seal: Seal of Junsei Chemical Co., Ltd. Saitama Plant] 1-6 Ohmanocho, Koshigaya-shi, Saitama, Testing Division, Saitama Plant, Junsei Chemical Co., Ltd. TEL: Koshigaya (62) 6161			

COPY

Governmental Commission Methanol	ME 58	<u>Certificate of Analysis</u>		No. 03244	
TO:		July 20, 1983			
Delivery No. 10		Testers	[seal: Uyama]		[seal: Tokuno]
Specimen:	Methanol (Methyl Alcohol)	Test Grade:	Pure Grade 1 grade		
Test Date:	July 17, 1983	Climate:	Weather:	Temp:	°C
Date of Mfg.:		Quantity:	14 kg x 10		
Lot No.:	8G1348	Remarks:			
Items		Standards	Assay Value		
Solubility in water		To pass test	Pass		
Water		Max. 0.3 %	0.012 %		
Non-volatile matter		Max. 0.003 %	trace		
Acid (as HCOOH)		Max. 0.004 %	0.0005 %		
Alkali (as NH ₃)		Max. 0.0005 %	trace		
Acetone, aldehyde (as CH ₃ COH ₃)		Max. 0.005 %	0.001%		
Ethyl alcohol		To pass test	pass		
Substances reducing permanganate		Max. 0.0015 %	pass		
Substances darkened by H ₂ SO ₄		To pass test	pass		
Boiling range (64-66 °C)		Min. 95 v/v %	pass		
ASSAY (by specific gravity)		Min. 99.6 v/v %	99.9 %		
Specific gravity (20/ 20 °C)		Max. 0.794	0.7930		
* Vinyl chloride		Max. 1 ppm	About 0.02 ppm		
* Formaldehyde		Max. 3 ppm	About 2.5 ppm or less		
DECISION	PASSED	[seal: Seal of Junsei Chemical Co., Ltd. Saitama Plant] 1-6 Ohmanocho, Koshigaya-shi, Saitama, Testing Division, Saitama Plant, Junsei Chemical Co., Ltd. TEL: Koshigaya (62) 6161			

07/21/83

COPY

Governmental Commission Methanol	ME 58	<u>Certificate of Analysis</u>		No. 03474	
TO:		September 8, 1983			
Delivery No. 11		Testers	[seal: Uyama]		[seal: Tokuno]
Specimen:	Methanol (Methyl Alcohol)	Test Grade:	Pure Grade 1 grade		
Test Date:	August 25, 1983	Climate:	Weather:	Temp:	°C
Date of Mfg.:		Quantity:	14 kg x 10		
Lot No.:	8H1562	Remarks:			
Items		Standards	Assay Value		
Solubility in water		To pass test	Pass		
Water		Max. 0.3 %	0.015 %		
Non-volatile matter		Max. 0.003 %	trace		
Acid (as HCOOH)		Max. 0.004 %	0.0003 %		
Alkali (as NH ₃)		Max. 0.0005 %	trace		
Acetone, aldehyde (as CH ₃ COH ₃)		Max. 0.005 %	0.001%		
Ethyl alcohol		To pass test	pass		
Substances reducing permanganate		Max. 0.0015 %	pass		
Substances darkened by H ₂ SO ₄		To pass test	pass		
Boiling range (64-66 °C)		Min. 95 v/v %	pass		
ASSAY (by specific gravity)		Min. 99.6 v/v %	99.9 %		
Specific gravity (20/ 20 °C)		Max. 0.794	0.7930		
* Vinyl chloride		Max. 1 ppm	About 0.02 ppm		
* Formaldehyde		Max. 3 ppm	About 2.5 ppm or less		
DECISION	PASSED	[seal: Seal of Junsei Chemical Co., Ltd. Saitama Plant] 1-6 Ohmanocho, Koshigaya-shi, Saitama, Testing Division, Saitama Plant, Junsei Chemical Co., Ltd. TEL: Koshigaya (62) 6161			

Governmental Commission Methanol	ME 58
--	----------

November 1, 1983

TO: _____

Testing Division, Saitama Plant,
Junsei Chemical Co., Ltd.
1-6 Ohmanochō, Koshigaya-shi,
Saitama,
TEL: (0489) 86-6161
[seal: Seal of Junsei Chemical Co., Ltd.
Saitama Plant]
[seal: Tokuno]

Delivery No. 12

Certificate of Analysis

Specimen: Pure Grade 1 Methanol (Methyl Alcohol)
Test Date: October 24, 1983
Quantity: 14 kg x 10
Lot No.: 8I4062
Tester: Nita
Supervisor: Tokuno

8J4062

<Items>		<Standards>	<Assay Value>
Solubility in water		Within limit	Within limit
Specific gravity (20/ 20 °C)		0.794 or less	0.7930
Fraction (64-65 °C)	v/v %	95 or more	pass
Water	%	0.3 or less	0.040
Non-volatile matter	%	0.003 or less	0.0003 or less
Acid	%	0.002 or less	0.0002
Alkali	%	0.0003 or less	0.0000
Ethanol		Within limit	Within limit
Substances reducing permanganate		Within limit	Within limit
Substances darkened by sulfate		Within limit	Within limit
Content	%	99.6 or more	99.9
Vinyl chloride		1 ppm or less	About 0.03 ppm
Formaldehyde		3 ppm or less	About 2.5 ppm or less

Governmental Commission Methanol	ME 58
--	----------

December 8, 1983

TO: *Mitsubishi Kasei Institute of Toxicology and Environmental Sciences*

[seal: Received]
Mitsubishi Kasei Institute of Toxicology and Environmental Sciences, Ltd
Testing Division, Saitama Plant,
Junsei Chemical Co., Ltd.
1-6 Ohmanochō, Koshigaya-shi,
Saitama,
TEL: (0489) 86-6161
[seal: Seal of Junsei Chemical Co., Ltd.
Saitama Plant]
[seal: Tokuno]

Delivery No. 13

Certificate of Analysis

Specimen: Pure Grade 1 Methanol (Methyl Alcohol)
Test Date: December 5, 1983
Quantity: 14 kg x 10
Lot No.: 8L1014
Tester: Nita
Supervisor: Tokuno

<Items>		<Standards>	<Assay Value>
Solubility in water		Within limit	Within limit
Specific gravity (20/ 20 °C)		0.794 or less	0.7930
Fraction (64-65 °C)	v/v %	95 or more	pass
Water	%	0.3 or less	0.009
Non-volatile matter	%	0.003 or less	0.0003 or less
Acid	%	0.002 or less	0.0002
Alkali	%	0.0003 or less	0.0000
Ethanol		Within limit	Within limit
Substances reducing permanganate		Within limit	Within limit
Substances darkened by sulfate		Within limit	Within limit
Content	%	99.6 or more	99.9
Vinyl chloride		1 ppm or less	About 0.015
Formaldehyde		3 ppm or less	About 2.5 or less

Governmental Commission Methanol	ME 59
--	----------

TO: _____

April 23, 1984

Testing Division, Saitama Plant,
Junsei Chemical Co., Ltd.
1-6 Ohmanochi, Koshigaya-shi,
Saitama,
TEL: (0489) 86-6161
[seal: Seal of Junsei Chemical Co., Ltd.
Saitama Plant]
[seal: Tokuno]

Delivery No. 14

Certificate of Analysis

Specimen: Pure Grade 1 Methanol (Methyl Alcohol)
Test Date: April 18, 1984
Quantity: 14 kg x 10
Lot No.: 9D1379
Tester: Nita
Supervisor: Tokuno

<Items>		<Standards>	<Assay Value>
Solubility in water		Within limit	Within limit
Specific gravity (20/ 20 °C)		0.794 or less	0.7930
Fraction (64-65 °C)	v/v %	95 or more	pass
Water	%	0.3 or less	0.035
Non-volatile matter	%	0.003 or less	0.0003 or less
Acid	%	0.002 or less	0.0004
Alkali	%	0.0003 or less	trace
Ethanol		Within limit	Within limit
Substances reducing permanganate		Within limit	Within limit
Substances darkened by sulfate		Within limit	Within limit
Content	%	99.6 or more	99.9
Vinyl chloride		1 ppm or less	About 0.07
Formaldehyde		3 ppm or less	About 2.5

Mr. Matsuura, Safety Institute

[seal: Namiki, 8/24/84, (Tada)]

Governmental Commission Methanol	ME 59
--	----------

08/24 10:41 AM JUNSEI SAITAMA #01 [seal: Takeda, 8/27/84,
(Kazu)]

August 24, 1984

TO: Mitsubishi Kasei Institute of Toxicology and Environmental Sciences

Testing Division, Saitama Plant,
Junsei Chemical Co., Ltd.
1-6 Ohmanochi, Koshigaya-shi,
Saitama,
TEL: (0489) 86-6161
[seal: Seal of Junsei Chemical Co., Ltd.
Saitama Plant]
[seal: Tokuno]

Certificate of Analysis

Specimen: Pure Grade 1 Methanol (Methyl Alcohol)
Test Date: August 6, 1984
Quantity: 14 kg x 10
Lot No.: 9H1091
Tester: Nita
Supervisor: Tokuno

<Items>		<Standards>	<Assay Value>
Solubility in water		Within limit	Within limit
Specific gravity (20/ 20 °C)		0.794 or less	0.7930
Fraction (64-65 °C)	v/v %	95 or more	pass
Water	%	0.3 or less	0.016
Non-volatile matter	%	0.003 or less	0.0003 or less
Acid	%	0.002 or less	0.0004
Alkali	%	0.0003 or less	trace
Ethanol		Within limit	Within limit
Substances reducing permanganate		Within limit	Within limit
Substances darkened by sulfate		Within limit	Within limit
Content	%	99.6 or more	99.9
Vinyl chloride		1 ppm or less	About 0.05
Formaldehyde		3 ppm or less	About 2.5 or less

Strain: Rats/ Mice Page - 1

<i>I</i>	Month/ Day (Date)			/ (Mon)		/ (Tue)		/ (Wed)		/ (Thu)		/ (Fri)		/ (Sat)		/ (Sun)				
	Recorder		Time		:		:		:		:		:		:		:			
Nursery	Temperature		22 ± 2 °C																	
	Differential pressure (+)		Positive pressure																	
	Automatic feed water pressure		0.3 kg/ cm ² or more																	
	Humidifier feed water pressure		kg/ cm ²																	
	Dionizer		Indicator																	
Temp. inside the Chamber	<i>No.</i> 1 (1000 ppm)		23 ± 2 °C																	
	2 (100 ppm)																			
	3 (10 ppm)																			
	4 (0 ppm)																			
	Temperature alarm °C → All function shutdown																			
Controller	Methanol Level		<i>No.</i> 1 (1000 ppm)																	
			2 (100 ppm)																	
			3 (10 ppm)																	
	Gain (ml/ min.)		<i>No. 1</i>	<i>No. 2</i>	<i>No. 3</i>															
	P (%)																			
	I (min.)																			
	D (min.)																			

2	Month/ Day		/ (Mon)	/ (Tue)	/ (Wed)	/ (Thu)	/ (Fri)	/ (Sat)	/ (Sun)
Operation Time	Operation shutdown time		:	:	:	:	:	:	:
	Operation start time		:	:	:	:	:	:	:
	Duration of shutdown		hr min.	hr min.	hr min.	hr min.	hr min.	hr min.	hr min.
	Duration of operation		hr min.	hr min.	hr min.	hr min.	hr min.	hr min.	hr min.
	Total operating time		hr min.	hr min.	hr min.	hr min.	hr min.	hr min.	hr min.
Chamber 4 (Contrast)	Flow rate	m ² / hr							
	Differential pressure (-)	10 ± 8 mmAq							
	Differential pressure alarm max.	18 mmAq							
	Differential pressure alarm min.	2 mmAq							
Chamber 3 (Low)	Differential pressure alarm auto restoration		mmAq						
	Flow rate	m ² / hr							
	Differential pressure (-)		10 ± 8 mmAq						
	Analyzer	Methanol Level	10 %						
		Range	/						
		ZERO	Before → after						
		SPAN	calibration						
	Sampling Pump	Sample flow rate (1 ml/ min.)							
		Change cock	Measure – (closed)						
	Methanol fluid level								

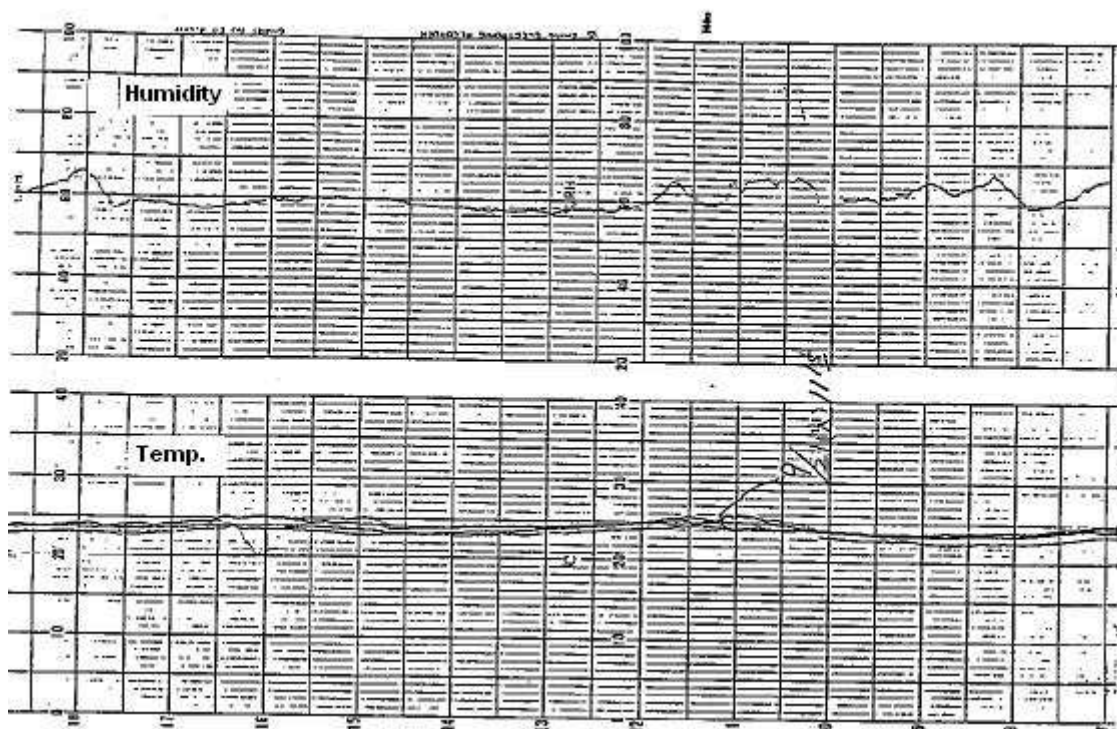
3	Month/ Day		/ (Mon)	/ (Tue)	/ (Wed)	/ (Thu)	/ (Fri)	/ (Sat)	/ (Sun)
Chamber 3 (Medium)	Flow rate		m ² / hr						
	Differential pressure (-)		10 ± 8 mmAq						
	Analyzer	Methanol Level	50 %						
		Range	/						
		ZERO	Before → after						
		SPAN	calibration						
	Sampling Pump	Sample flow rate (1 ml/ min.)							
		Change cock	Measure – (closed)						
	Methanol fluid level								
Chamber 3 (High)	Flow rate		m ² / hr						
	Differential pressure (-)		10 ± 8 mmAq						
	Analyzer	Methanol Level	666 %						
		Range	/						
		ZERO	Before → after						
		SPAN	calibration						
	Sampling Pump	Sample flow rate (1 ml/ min.)							
		Change cock	Measure – (closed)						
	Methanol fluid level								

[illegible]

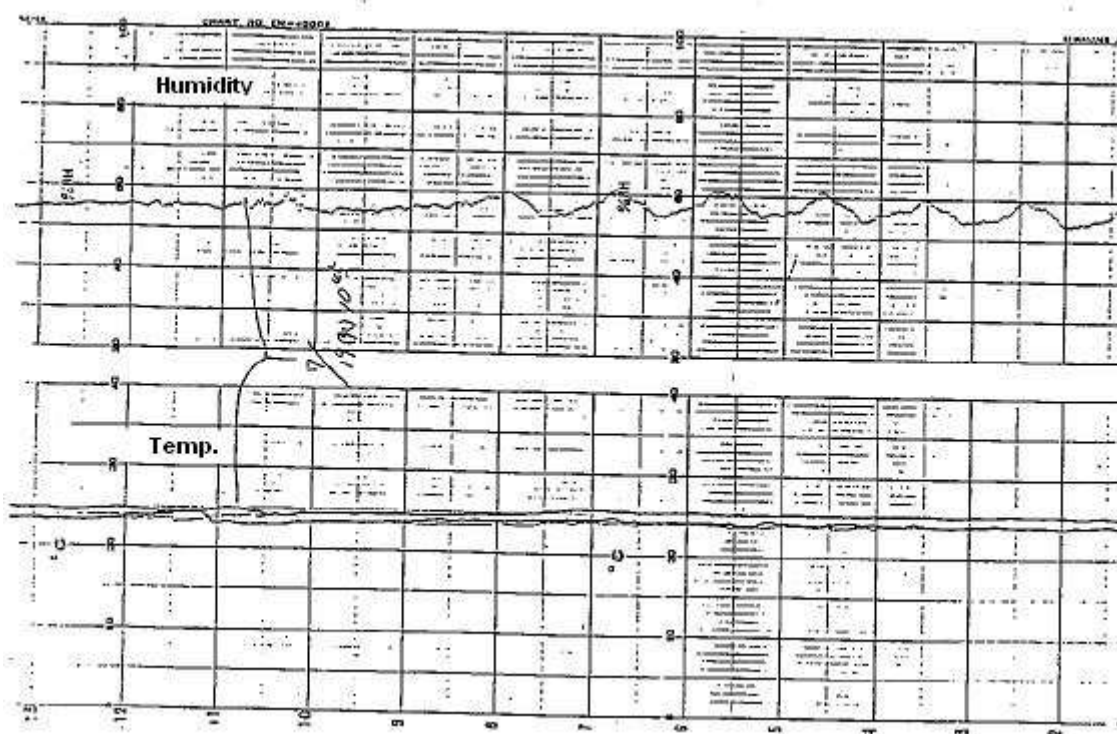
Daily Inspection Chart for Methanol Inhalation Facility (3)

[illegible]

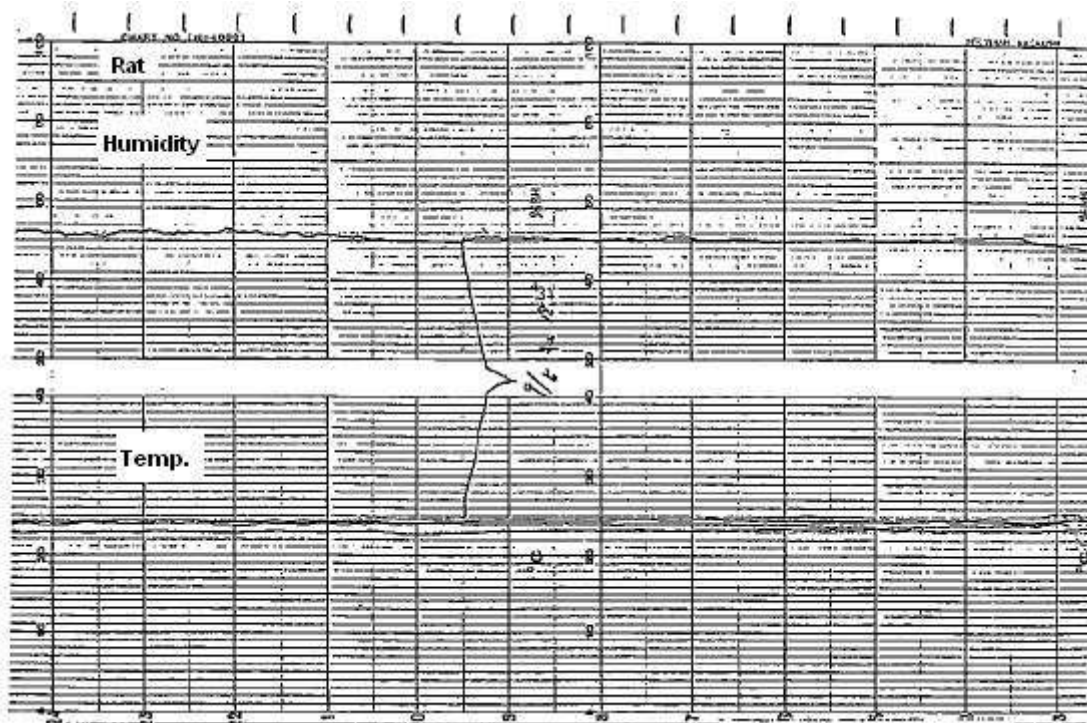
Support Document 5: A Record of Temperature and Humidity Inside the Exposure Chamber (One Example)



(Recorded on September 21, 1982)



(Recorded on July 19, 1983)



(Recorded on September 5, 1984)

Support Document 6: Details of Animal Care and Management

1. Method of Feeding and Providing Water

(1) Method of Feeding

Autoclave-sterilized solid diet for mice, rats and hamsters (CRF-1 manufactured by Charles River Japan) was freely available in a feeder attached to each inhalation chamber.

When necessary, food consumption was monitored using a special feeder designed specifically for measuring the amount of intake.

The nutritional design of the food allows for autoclave sterilization. See attachment for food ingredients.

(2) Method of Providing Water

Tap water that has been filtered through a filter with 5 μ filtration accuracy and then ran through a ultra violet water sterilizer (T-SS-11-B manufactured by Tokiwa Kagaku Kikai) was freely available in a water feeder during acclimation and quarantine period and then in an automatic feedwater unit (with touch-sensitive mouthpiece) attached to each inhalation chamber after test animals were moved to the chambers.

The quality of tap water used for drinking was tested every six months. See attachment for test results.

2. Entering the Inhalation Laboratory

Entry to the barrier system (hereafter, “BS”) is done in the following manner: Remove clothing except for underwear at dressing room, and wash and sterilize face, forearms, hand and fingers, lower legs and toes. Then, at the dressing room on the BS side, wear a dust-free hat and a suit, mask, gloves, socks and shoes, and enter the BS. During above, one must pass through four separate rooms, and this setup considerably lowers the chance of contaminating the BS by infection, etc.

The photograph of the outfit to be worn inside the BS is shown. Details of entry procedure to the BS are also shown at the end.

3. Sterilizing Method of Equipments, etc.

All equipments used within the BS are disinfected and sterilized by one of the following methods:

(a) Autoclave

All items that can be sterilized by high-pressure steam were sterilized in autoclave for 15 minutes under 1.2 kg/cm^2 , 125°C .

Manufacturer: Uono, Ltd.	Capacity:	$2.049 \text{ m}^3 \times 1 \text{ unit}$
		$0.115 \text{ m}^3 \times 1 \text{ unit}$

(b) Ethylene oxide gas

Anprolene (Manufactured by Andersen Products, Inc.)

(c) Chemical disinfection

Items that cannot be sterilized by methods (a) or (b) were disinfected by one of the following chemicals prior to taking inside the BS:

- Microcut (EL K.K.)
- Sodium hypochlorite solution (Tsuruchlone, Tsurumi Soda, Co., Ltd.)
- Hibitane (5 % Hibitane solution, Sumitomo Chemical Co., Ltd.)

The effect of autoclave sterilization was tested by either Sterilization Tespor S (Eiken Chemical Co., Ltd.) or Autoclave Tape (Hirasawa Seisakusho), and the effect of ethylene oxide gas sterilization was tested by either dosimeter (Andersen Products, Inc.) or Sterilization Tespor S (Eiken Chemical Co., Ltd.).

4. Barrier System Maintenance

- | | | |
|--|------------------------------------|--|
| (a) Frequency of replacing the cages: | Acclimation and quarantine period: | Once/ wk |
| | Exposure period: | Once/ 2 wks |
| (b) Frequency of replacing the feeders and water feeders: | | Once/ wk |
| (c) Frequency of replacing the trays for inhalation cages: | | Twice/ wk (mice) |
| | | 3 times / wk (rats) |
| (d) Frequency of rotating the cages: | Once/ 2 wks | (Rotation of the location of cage within the chamber, i.e., between upper, middle and lower layer) |

(e) Cleaning and Disinfection

- Exposure chamber: Once/ 2 wks (during cage replacement); Chemical used: Microcut
- Hand and finger: As needed. Chemical used: Microcut
- Inhalation lab floor: Upon completion of work; Chemical used: Sodium hypochlorite solution 240 ppm
- Inhalation lab wall/ ceiling: Once/ month; Chemical used: Sodium hypochlorite solution 240 ppm
- Sterilization preparation room, bathroom and hallway:
Once a day dry bath using Microcut. In addition, during the night time, automatically spray a mixture of Microcut and Hibitane for 15 minutes once a day.

- Backup animal room: Prior to bringing in animals as well as upon completion of the test, spray sodium hypochlorite solution (500 ppm) without supplying or evacuating air (leave for at least one day or longer)
- Dressing room: Constantly irradiate with ultra violet light



Outfit inside the Barrier System

2/4/83 in...

Analysis ReportNo. _____
(Page 1 of 3)TO: Research Institute,
Mitsubishi Chemical Corporation3-6-10 Azusawa, Itabashi-ku, Tokyo 174
Bioresearch Laboratory,
Bioindustry Division
Oriental Yeast Co., Ltd.Specimen: November 1982 installment
Requester: _____

TEL: 03 (968) 1111

Implementation Method: In-house Analysis Standards

Date of Report		1 / 31 / 1983	
	[seal: Suwa]		[seal: Kitamura]
Tester	Reporter	Mgr.	GM

(%)

Test Item Specimen	Moisture Content	Crude Protein	Crude Fat	Crude Ash	Crude Fiber	Nitrogen-free Extract
MF Lot 11-67	8.3	24.9	5.8	6.1	3.2	51.7
NMF 11-51	7.7	29.1	5.8	8.3	4.7	44.4
CMF 11-52	8.8	29.6	8.5	6.4	3.9	42.8
CRF-1 11-58	8.2	23.1	6.2	6.3	3.6	52.6
ORC4 11-54	7.8	20.4	3.1	9.0	14.2	45.5
RC4 11-60	7.6	21.8	2.8	8.7	14.3	44.8
GC4 11-54	7.2	23.9	4.4	8.6	13.1	42.8
AB 11-51	8.4	26.2	7.1	4.4	1.1	52.8
DB 11-52	8.1	29.0	5.8	5.7	1.3	50.1
DS 11-52	7.8	28.8	8.5	6.1	3.2	45.6
CS 11-65	6.3	33.5	10.4	7.4	3.2	39.2
			Blank below			
Report						

Analysis ReportNo. _____
(Page 2 of 3)

TO: _____

3-6-10 Azusawa, Itabashi-ku, Tokyo 174
 Bioresearch Laboratory,
 Bioindustry Division
 Oriental Yeast Co., Ltd.
 TEL: 03 (968) 1111

Specimen: November 1982 installment
Requester:

Implementation Method: In-house Analysis Standards
Data marked with asterisk are based on
Japan Food Research Laboratories

Date of Report			
			[seal: Kitamura]
Tester	Reporter	Mgr.	GM

Specimen \ Test Item	NMF (11-51)	CRF-1 (11-58)	ORC4 (11-54)			Detection Limit (ppm)
Pb (ppm)	0.54	0.47	0.86			
Cd (ppm)	0.12	0.06	0.06			
* As (ppm)	0.6	0.4	0.2			
Cr (Total) (ppm)	0.39	0.35	1.27			
HG (Total) (ppm)	0.01	0.01	0.01			
Nitrite (ppm)	1.0	0.8	Not detected			0.3
Aflatoxin (B ₁ B ₂ G ₁ G ₂)	Not detected	Not detected	Not detected			0.01
* PCB (Total)	Not detected	Not detected	Not detected			0.01
* BHC (Total)	Not detected	Not detected	Not detected			0.05
* Aldrin	Not detected	Not detected	Not detected			0.01
* Heptachlor	Not detected	Not detected	Not detected			0.01
* Dieldrin	Not detected	Not detected	Not detected			0.01
* DDT (Total)	Not detected	Not detected	Not detected			0.1
Parathion	Not detected	Not detected	Not detected			0.01
Malathion (ppm)	0.94	0.92	0.54			
Report						

Analysis Report

No. _____
(Page 3 of 3)

TO: _____

3-6-10 Azusawa, Itabashi-ku, Tokyo 174
 Bioresearch Laboratory,
 Bioindustry Division
Oriental Yeast Co., Ltd.
 TEL: 03 (968) 1111

Specimen: November 1982 installment
Requester: _____

Implementation Method: In-house Analysis Standards

Date of Report			
			[seal: Kitamura]
Tester	Reporter	Mgr.	GM

		(piece/ g)				
Specimen	Test Item	General Viable Count	Coli Group	Salmonella	Fungi	
MF	Lot 11-67	2.0 x 10 ⁴	0	0	1	
NMF	11-51	5.0 x 10 ³	0	0	2	
CRF-1	11-58	1.2 x 10 ⁴	0	0	5	
ORC4	11-54	1.5 x 10 ⁴	0	0	2	
RC4	11-60	2.5 x 10 ⁴	0	0	5	
GC4	11-54	3.7 x 10 ⁴	0	0	12	
DS	11-52	2.6 x 10 ²	0	0	5	
		Blank below				
Report						

Test Item Specimen		(%)					
		Moisture Content	Crude Protein	Crude Fat	Crude Ash	Crude Fiber	Nitrogen-free Extract
MF	Lot 58-09-56	8.1	24.8	5.8	6.2	3.0	52.1
NMF	58-09-55	7.1	29.3	5.5	7.6	4.4	46.1
CMF	58-09-52	7.1	29.2	8.7	6.6	3.2	45.2
CRF-1	58-09-56	7.5	23.5	6.1	6.7	3.3	52.9
ORC4	58-09-69	7.3	19.9	3.1	8.8	13.9	47.0
RC4	58-09-57	7.0	22.5	3.7	8.9	13.9	44.0
GC4	58-09-64	6.4	24.1	4.3	8.7	12.7	43.8
AB	58-09-51	9.4	27.0	6.8	4.5	1.0	51.3
DB	58-09-52	7.6	28.8	5.1	6.1	1.1	51.3
DS	58-09-64	7.3	28.1	8.2	7.7	3.5	45.2
CS	58-09-70	7.0	32.9	10.9	8.2	3.4	37.6
				Blank below			
Report							

Analysis ReportNo. _____
(Page 2 of 3)

TO: _____

3-6-10 Azusawa, Itabashi-ku, Tokyo 174
 Bioresearch Laboratory,
 Bioindustry Division
 Oriental Yeast Co., Ltd.
 TEL: 03 (968) 1111

Specimen: September 1983 installment
Requester:

Implementation Method: In-house Analysis Standards*Data marked with asterisk are based on**Japan Food Research Laboratories*

Specimen \ Test Item	NMF (09-55)	CRF-1 (09-56)	ORC4 (09-64)			Detection Limit (ppm)
Pb	0.27	0.32	0.54			
Cd	0.10	0.06	0.01			
* As	0.5	0.3	0.2			
Cr (Total)	0.46	0.27	0.99			
HG (Total)	0.01	0.01	0.01			
Nitrite	0.9	0.8	0.9			
Aflatoxin (B ₁ B ₂ G ₁ G ₂)	Not detected	Not detected	Not detected			0.05
* PCB (Total)	Not detected	Not detected	Not detected			0.01
* BHC (Total)	Not detected	Not detected	Not detected			0.05
* Aldrin	Not detected	Not detected	Not detected			0.01
* Heptachlor	Not detected	Not detected	Not detected			0.01
* Dieldrin	Not detected	Not detected	Not detected			0.01
* DDT (Total)	Not detected	Not detected	Not detected			0.05
Parathion	Not detected	Not detected	Not detected			0.01
Malathion	0.57	0.63	0.33			
Report						

		(%)					
Test Item Specimen		Moisture Content	Crude Protein	Crude Fat	Crude Ash	Crude Fiber	Nitrogen-free Extract
MF	Lot 59-03-58	8.5	24.4	5.4	6.3	3.5	51.9
NMF	59-03-57	7.9	29.1	5.4	8.1	4.6	44.9
CMF	59-03-51	7.9	29.4	9.1	6.6	3.4	43.6
CRF-1	59-03-51	8.6	22.3	6.1	6.5	3.4	53.1
RC4	59-03-62	7.2	22.4	3.1	8.5	13.8	45.0
ORC4	59-03-69	8.2	20.0	3.2	8.7	14.5	45.4
GC4	59-03-78	7.4	24.3	4.4	8.6	13.0	42.3
DB	59-03-51	7.7	28.4	5.3	6.1	1.2	51.3
DS	59-03-51	7.2	27.2	8.8	7.2	3.8	45.8
CS	59-03-63	5.3	33.7	9.9	8.5	3.2	39.4
NIH	59-03-55	7.4	27.3	7.2	7.4	3.6	47.1
				Blank below			
Report	I hereby certify that the results of analysis above are records of analysis performed in accordance with set procedures. OAU: <i>Tomio Suwa</i>						

Analysis ReportNo. _____
(Page 2 of 3)

TO: _____

3-6-10 Azusawa, Itabashi-ku, Tokyo 174
 Bioresearch Laboratory,
 Bioindustry Division
 Oriental Yeast Co., Ltd.
 TEL: 03 (968) 1111

Specimen: March 1984 installment

Requester: _____

Implementation Method: In-house Analysis Standards*Data marked with asterisk are based on**Japan Food Research Laboratories*

Specimen \ Test Item	NMF (03-57)	CRF-1 (03-51)				Detection Limit (ppm)
Pb	0.27	0.22				
Cd	0.08	0.06				
* As	0.6	0.3				
Cr (Total)	0.40	0.30				
HG (Total)	0.02	0.01				
Nitrite	0.9	1.4				
Aflatoxin (B ₁ B ₂ G ₁ G ₂)	Not detected	Not detected				0.005
* PCB (Total)	Not detected	Not detected				0.01
* BHC (Total)	Not detected	Not detected				0.05
* Aldrin	Not detected	Not detected				0.01
* Heptachlor	Not detected	Not detected				0.01
* Dieldrin	Not detected	Not detected				0.01
* DDT (Total)	Not detected	Not detected				0.05
Parathion	Not detected	Not detected				0.01
Malathion	0.84	1.23				
Report						

Specimen \ Test Item		(piece/ g)					
		General Viable Count	Coli Group	Salmonella	Fungi		
MF	Lot 59-03-58	7.3 x 10 ³	0	0	3		
NMF	59-03-57	6.8 x 10 ³	0	0	1		
CRF-1	59-03-51	2.2 x 10 ⁴	0	0	5		
RC4	59-03-62	3.7 x 10 ⁵	0	0	0		
GC4	59-03-78	1.0 x 10 ⁵	0	0	1		
DB	59-03-51	4.2 x 10 ²	0	0	1		
DS	59-03-51	6.1 x 10 ¹	0	0	0		
CS	59-03-63	6.8 x 10 ²	0	0	0		
			Blank below				
Report							

		(%)					
Test Item Specimen		Moisture Content	Crude Protein	Crude Fat	Crude Ash	Crude Fiber	Nitrogen-free Extract
MF	Lot 59-09-53	6.8	25.1	5.8	6.5	3.1	52.7
NMF	59-09-55	6.7	28.6	5.5	7.8	4.0	47.4
CMF	59-09-51	7.8	29.3	8.5	6.6	3.3	44.5
CRF-1	59-09-52	7.4	23.4	6.1	6.6	3.4	53.1
RC4	59-09-63	7.4	21.4	2.7	8.6	13.3	46.6
ORC4	59-09-69	7.7	19.1	2.7	8.7	15.0	46.8
GC4	59-09-75	7.0	23.7	3.6	8.7	12.7	44.3
AB	59-09-55	8.2	25.0	6.6	4.5	1.0	54.7
DS	59-90-57	7.3	27.2	8.6	7.3	3.1	46.5
				Blank below			
Report	I hereby certify that the results of analysis above are records of analysis performed in accordance with set procedures. OAU: <i>Tomio Suwa</i>						

Analysis ReportNo. _____
(Page 2 of 3)

TO: _____

3-6-10 Azusawa, Itabashi-ku, Tokyo 174
 Bioresearch Laboratory,
 Bioindustry Division
 Oriental Yeast Co., Ltd.
 TEL: 03 (968) 1111

Specimen: September 1984 installment
Requester: _____

Implementation Method: In-house Analysis Standards*Data marked with asterisk are based on**Japan Food Research Laboratories*

Specimen \ Test Item	NMF (09-55)	CRF-1 (09-52)	GC4 (09-75)			Detection Limit (ppm)
Pb	0.22	0.25	0.55			
Cd	0.06	0.05	0.04			
* As	0.6	0.4	0.2			
Cr (Total)	0.64	0.39	0.87			
HG (Total)	0.01	0.01	0.01			
Nitrite	0.6	0.6	0.4			
Aflatoxin (B ₁ B ₂ G ₁ G ₂)	Not detected	Not detected	Not detected			0.005
* PCB (Total)	Not detected	Not detected	Not detected			0.01
* BHC (Total)	Not detected	Not detected	Not detected			0.05
* Aldrin	Not detected	Not detected	Not detected			0.01
* Heptachlor	Not detected	Not detected	Not detected			0.01
* Dieldrin	Not detected	Not detected	Not detected			0.01
* DDT (Total)	Not detected	Not detected	Not detected			0.05
Parathion	Not detected	Not detected	Not detected			0.01
Malathion	1.04	0.75	0.39			
Report						

WATER QUALITY TEST REPORT

No. M57-200 (2)

November 2, 1982

TO: Facility Section, Research Institute, Mitsubishi Chemical

Mitsubishi Kasei Institute
of Toxicology and Environmental Sciences
Director of Laboratory, Yoshiaki Suzuki

Following are the results of water quality test requested by your company on October 18, 1982.

Name of Structure: Facility Section, Research Institute, Mitsubishi Chemical

Location: 1000 Kamoshida-cho, Midori-ku, Yokohama

Sampling Location: Drinking water terminal hydrant

Date and Time of Sampling: October 18, 12:00 PM Raw Water Type: City water

Reason for Request: To test the quality after cleaning the drinking water tank

Residual Chlorine at the Time of Sampling			Isolation – mg/ ℓ (Binding – mg/ ℓ)		
Item	Quality Standards	Test Result	Item	Quality Standards	Test Result
1. Nitrate-nitrogen & nitrite-nitrogen	Less than 10 mg/ liter	1.02	15. Cadmium	Less than 0.01 mg/ liter	< 0.01
2. Chloride ion	Less than 200 mg/ liter	7.0	16. Arsenic	Less than 0.05 mg/ liter	< 0.05
3. Potassium permanganate consumption rate	Less than 10 mg/ liter	0.81	17. Fluorine	Less than 0.8 mg/ liter	< 0.2
4. General bacteria	Less than 100 mg/ liter	0	18. Hardness	Less than 300 mg/ liter	63
5. Coli group	Not to be detected	Negative	19. Evaporation residue	Less than 500 mg/ liter	107
6. Cyanide ion	Not to be detected	< 0.001	20. Phenols	Less than 0.005 mg/ liter	< 0.005
7. Mercury	Not to be detected	< 0.0005	21. Negative ion surfactant	Less than 0.5 mg/ liter	< 0.1
8. Organic phosphorus	Not to be detected	< 0.1	22. pH	5.8-8.6	7.6 @ 20°C
9. Copper	Less than 1.0 mg/ liter	< 0.04	23. Odor	Not to be abnormal	Normal
10. Steel	Less than 0.3 mg/ liter	< 0.05	24. Taste	Not to be abnormal	Normal
11. Manganese	Less than 0.3 mg/ liter	< 0.05	25. Color	Less than Degree 2	Deg. 1
12. Zinc	Less than 1.0 mg/ liter	< 0.02	26. Turbidity	Less than Degree 1	< Deg. 1
13. Lead	Less than 0.1 mg/ liter	0.07	27. Ammoniac nitrogen		---
14. Hexavalent chromium	Less than 0.05 mg/ liter	< 0.05			
Decision	Based on above result, the water quality is compliant to the standards of Waterworks Law				
Date of Receipt of Specimen	October 18, 1:00 PM		Test Period: October 18 - 29		
Test Location	Mitsubishi Kasei Institute of Toxicology and Environmental Sciences Ltd 1000 Kamoshida-cho, Midori-ku, Yokohama, 227 TEL: (045) 962-1211				

WATER QUALITY TEST REPORT

No. A83001 (2)

May 4, 1983

TO: Toxicology Group, Mitsubishi Kasei Institute of Toxicology and Environmental Sciences, Ltd.

Mitsubishi

Kasei Institute of Toxicology and Environmental Sciences, Ltd.

Director of Laboratory, Yoshiaki Suzuki

[seal: Seal of Safety Institute]

[seal: *Mitsubishi Kasei Institute of Toxicology and Environmental Sciences, Ltd*]

Following are the results of water quality test requested by your company on April 12, 1983.

Name of Structure: Animal Wing, Safety Institute

Location: 1000 Kamoshida-cho, Midori-ku, Yokohama

Sampling Location: Drinking water terminal hydrant 002

Date and Time of Sampling: April 12, 12:00 PM

Raw Water Type: Drinking water

Reason for Request: Periodic inspection

Residual Chlorine at the Time of Sampling			Isolation 0.3 mg/ ℓ (Binding 0.1 mg/ ℓ)		
Item	Quality Standards	Test Result	Item	Quality Standards	Test Result
1. Nitrate-nitrogen & nitrite-nitrogen	Less than 10 mg/ liter	0.68	15. Cadmium	Less than 0.01 mg/ liter	< 0.005
2. Chloride ion	Less than 200 mg/ liter	7.0	16. Arsenic	Less than 0.05 mg/ liter	< 0.01
3. Potassium permanganate consumption rate	Less than 10 mg/ liter	1.2	17. Fluorine	Less than 0.8 mg/ liter	< 0.06
4. General bacteria	Less than 100 mg/ liter	4	18. Hardness	Less than 300 mg/ liter	53.7
5. Coli group	Not to be detected	Negative	19. Evaporation residue	Less than 500 mg/ liter	114
6. Cyanide ion	Not to be detected	< 0.01	20. Phenols	Less than 0.005 mg/ liter	< 0.005
7. Mercury	Not to be detected	< 0.0005	21. Negative ion surfactant	Less than 0.5 mg/ liter	< 0.1
8. Organic phosphorus	Not to be detected	< 0.1	22. pH	5.8-8.6	7.8 @ 22°C
9. Copper	Less than 1.0 mg/ liter	< 0.01	23. Odor	Not to be abnormal	Normal
10. Steel	Less than 0.3 mg/ liter	0.02	24. Taste	Not to be abnormal	Normal
11. Manganese	Less than 0.3 mg/ liter	< 0.01	25. Color	Less than Degree 2	< Deg. 1
12. Zinc	Less than 1.0 mg/ liter	0.03	26. Turbidity	Less than Degree 1	< Deg. 1
13. Lead	Less than 0.1 mg/ liter	< 0.01	27. Ammoniac nitrogen		< 0.03
14. Hexavalent chromium	Less than 0.05 mg/ liter	< 0.05			
Decision	Based on above result, the water quality is compliant to the standards of Waterworks Law				
Date of Receipt of Specimen	April 12, 1:00 PM		Test Period: April 12 - 26		
Test Location	Mitsubishi Kasei Institute of Toxicology and Environmental Sciences, Ltd 1000 Kamoshida-cho, Midori-ku, Yokohama, 227 TEL: (045) 962-1211				

WATER QUALITY TEST REPORT

No. A84003 ([illegible])

March 12, 1984

TO: Toxicology Group, Mitsubishi Kasei Institute of Toxicology and Environmental Sciences, LtdMitsubishi Kasei Institute of Toxicology
and Environmental Sciences, Ltd

Director of Laboratory, Yoshiaki Suzuki

[seal: Seal of Safety Institute]

[seal: *Mitsubishi Kasei Institute of Toxicology and Environmental Sciences, Ltd*]

Following are the results of water quality test requested by your company on February 20, 1984.

Name of Structure: Animal Wing Location: 1000 Kamoshida-cho, Midori-ku, Yokohama

Sampling Location: B-201

Date and Time of Sampling: February 20, 10:00 AM

Raw Water Type: City water

Reason for Request: Periodic inspection

Residual Chlorine at the Time of Sampling			Isolation 0.2 mg/ ℓ (Binding 0.2 mg/ ℓ)		
Item	Quality Standards	Test Result	Item	Quality Standards	Test Result
1. Nitrate-nitrogen & nitrite-nitrogen	Less than 10 mg/ liter	1.04	15. Cadmium	Less than 0.01 mg/ liter	< 0.001
2. Chloride ion	Less than 200 mg/ liter	9.1	16. Arsenic	Less than 0.05 mg/ liter	< 0.005
3. Potassium permanganate consumption rate	Less than 10 mg/ liter	1.38	17. Fluorine	Less than 0.8 mg/ liter	< 0.2
4. General bacteria	Less than 100 mg/ liter	0	18. Hardness	Less than 300 mg/ liter	60.9
5. Coli group	Not to be detected	Negative	19. Evaporation residue	Less than 500 mg/ liter	133
6. Cyanide ion	Not to be detected	< 0.01	20. Phenols	Less than 0.005 mg/ liter	< 0.005
7. Mercury	Not to be detected	< 0.0005	21. Negative ion surfactant	Less than 0.5 mg/ liter	< 0.1
8. Organic phosphorus	Not to be detected	< 0.03	22. pH	5.8-8.6	7.3 @ 20°C
9. Copper	Less than 1.0 mg/ liter	0.01	23. Odor	Not to be abnormal	Normal
10. Steel	Less than 0.3 mg/ liter	0.03	24. Taste	Not to be abnormal	Normal
11. Manganese	Less than 0.3 mg/ liter	< 0.01	25. Color	Less than Degree 2	< Deg. 1
12. Zinc	Less than 1.0 mg/ liter	0.02	26. Turbidity	Less than Degree 1	< Deg. 1
13. Lead	Less than 0.1 mg/ liter	< 0.01	27. Ammoniac nitrogen		< 0.03
14. Hexavalent chromium	Less than 0.05 mg/ liter	< 0.05			
Decision	Based on above result, the water quality is compliant to the standards of Waterworks Law				
Date of Receipt of Specimen	February 20, 1:00 PM		Test Period: February 20 – March 8		
Test Location	Mitsubishi Kasei Institute of Toxicology and Environmental Sciences, <u>Ltd</u> 1000 Kamoshida-cho, Midori-ku, Yokohama, 227 TEL: (045) 962-1211				

WATER QUALITY TEST REPORT

No. A84006 (3)

July 4, 1984

TO: Toxicology Group, Mitsubishi Kasei Institute of Toxicology and Environmental Sciences, Ltd.Mitsubishi Kasei Institute of Toxicology
and Environmental Sciences, Ltd

Director of Laboratory, Yoshiaki Suzuki

[seal: Seal of Safety Institute]

[seal: Mitsubishi Kasei Institute of Toxicology and Environmental Sciences, Ltd]

Following are the results of water quality test requested by your company on June 18, 1984.

Name of Structure: Animal Wing Location: 1000 Kamoshida-cho, Midori-ku, Yokohama

Sampling Location: 003 B-201

Date and Time of Sampling: June 18, 3:00 PM

Raw Water Type: City water

Reason for Request: Periodic inspection

Residual Chlorine at the Time of Sampling			Isolation 0.1 mg/ ℓ (Binding 0.2 mg/ ℓ)		
Item	Quality Standards	Test Result	Item	Quality Standards	Test Result
1. Nitrate-nitrogen & nitrite-nitrogen	Less than 10 mg/ liter	0.82	15. Cadmium	Less than 0.01 mg/ liter	---
2. Chloride ion	Less than 200 mg/ liter	7.2	16. Arsenic	Less than 0.05 mg/ liter	---
3. Potassium permanganate consumption rate	Less than 10 mg/ liter	1.6	17. Fluorine	Less than 0.8 mg/ liter	---
4. General bacteria	Less than 100 mg/ liter	3	18. Hardness	Less than 300 mg/ liter	63.8
5. Coli group	Not to be detected	Negative	19. Evaporation residue	Less than 500 mg/ liter	133
6. Cyanide ion	Not to be detected	---	20. Phenols	Less than 0.005 mg/ liter	---
7. Mercury	Not to be detected	---	21. Negative ion surfactant	Less than 0.5 mg/ liter	---
8. Organic phosphorus	Not to be detected	---	22. pH	5.8-8.6	7.5 @ 25 °C
9. Copper	Less than 1.0 mg/ liter	0.01	23. Odor	Not to be abnormal	Normal
10. Steel	Less than 0.3 mg/ liter	0.05	24. Taste	Not to be abnormal	Normal
11. Manganese	Less than 0.3 mg/ liter	---	25. Color	Less than Degree 2	< Deg. 1
12. Zinc	Less than 1.0 mg/ liter	0.01	26. Turbidity	Less than Degree 1	< Deg. 1
13. Lead	Less than 0.1 mg/ liter	---	27. Ammoniac nitrogen		---
14. Hexavalent chromium	Less than 0.05 mg/ liter	---			
Decision	Based on above result, the water quality is compliant to the standards of Waterworks Law				
Date of Receipt of Specimen	June 18, 3:00 PM		Test Period: June 18 - 29		
Test Location	Mitsubishi Kasei Institute of Toxicology and Environmental Sciences, <u>Ltd</u> 1000 Kamoshida-cho, Midori-ku, Yokohama, 227 TEL: (045) 962-1211				

How to Enter and Exit from the BS in the Animal Wing B

1. How to Enter the Room

When entering the animal room within BS, make sure to pay sufficient attention to hygiene control and adhere to the following rules as the room is used to keep SPF animals for a long period of time.

- 1) If suffering from respiratory infection, do not enter the room.
- 2) Ones worked at an animal room other than SPF animal room are prohibited to enter the room to prevent infection.
- 3) If suffering from an injury that requires a bandage, refrain from entering the room, as a general rule. If entry cannot be avoided, seek for supervisor's instruction.
- 4) If wearing a band-aid, etc., remove it at the dressing room in the contaminated side and retreat the wound at the dressing room in the clean side.
- 5) Do not forget to turn off/ on the sterilizing lamp when entering/ exiting each room. Make sure not to look at the sterilizing lamp directly with naked eyes.
- 6) When exiting the room, make sure that the door is closed.

2. How to Enter the BS

Change the entry sign to "Occupied."

Prior to entering the dressing room in the contaminated side, take off the shoes and put them on the rack.

(1) Dressing room in the contaminated side (divided by gender)

- ☐ Turn off the sterilizing lamp and turn on the fluorescent light.
- ☐ Remove clothing except for minimum required underwear and eye glasses, and put them on the shelf.
- ☐ If wearing a long hair and the hair may come out of the hat, secure it with pin, etc.
- ☐ The shower room can only hold up to three people at a time. Remember this when entering the shower room.

(2) Shower room (divided by gender)

- ☐ Carefully wash the arms and legs (elbow to finger tips and knees to toes) using a brush with a medicated soap (wash between fingers and nails as well), and rinse with water. In principle, wash the face as well.

- Using sterilized paper towels, wipe off water from extremities (i.e., hands and fingers/ toes) towards the body. Wipe the section closest to the contaminated section last.
- Prepare a chemical bath in the sink (200 x Hibitane solution), and sprinkle the chemical solution to faucet, shower handle, tip of toes and the floor.
- Rinse the eye glasses with water and wipe with sterilized paper towel.
- Using Hibitane and alcohol immersed cotton, wipe hands and fingers as well as the door knob on the shower room door in the clean side.
- Make sure no one is in the dressing room in the clean side and proceed to the room. Pay attention not to simultaneously open the door to the hallway and the door to the shower room in the clean side dressing room.

(3) Dressing room in the clean side (divided by gender)

Wear sterilized clothing here.

- Turn off sterilizing lamp and turn on fluorescent lamp.
- Carefully wipe off water on feet using paper towels.
- Put on the hat and then the mask. (Conversation is strictly prohibited until the mask is put on)
- Wear suit, socks, athletic shoes and rubber gloves.
- Go out to the hallway. Make sure to close the door. Turn off the fluorescent lamp and turn on the sterilizing lamp.

3. How to Enter and Exit from the Animal Room

(1) Entry procedure

As a general rule, enter the cage storage, food storage, and then animal room, and avoid as much as possible to enter other clean areas (cleaning workroom, cage storage, food storage) as much as possible after leaving any animal room.

4. How to Leave the BS

- (1) The hallway → bathroom → dressing room in the contaminated side → outside of barrier
- (2) Take all the clothes off and put them in the box by the entry.
- (3) Return the entry sign to original display.
- (4) The last person to leave must make sure no one else is left, and then turn off the fluorescent lamp for the BS hallway.

Support Document 7: Results of Antibody Test on Pathogenic Microorganisms

Results of Infection Tests on Mice and Rats (Serological Reaction) Test No. 1: Blood sampling on February 2, 1983 (5 months into the study)

Exp. No.	83-0216
Source	Mitsubishi-Kasei (Abe)

E: Ectromelia (Vaccinia)-CF
J: MHV-JHM (MHV-4)-CF
M: MHV-2-CF
S: Sendai-CF
Bb: Bordetella bronchiseptica-CF
Mp: Mycoplasma pulmonis-CF

Bp: Bacillus piliformis (Tyzzer)-CF
St: Salmonella typhimurium-AG
Ck: Corynebacterium kutscheri-AG

Positivity at 1:5

Group	Number of test sera	Number (%) of sera positive for :										
		E	J	M	S	Bb	Mp	Bp (H)	Bp (M)	Bp (R)	St	Ck
Rat :1-16*	16											
Rat :27-29	3											
Mouse:17-26 (B6C3F1)	10							0				
Total	29											

*

Date of Request	Specimen No.	Date of Blood Sampling	Experiment/ ID Code No.	Animal Type/ Strain	Gender	Age	Living Condition	Room No.	Tester
2/14/1983	1	11/01/82	Kukiko No. 1	Wister	Male		S → C	E Wing	Takeda
Dispatch	2	11/01/82	Kukiko No. 2	Wister	Male		S → C	E Wing	Takeda
	3	11/01/82	Kukiko No. 3	Wister	Male		S → C	E Wing	Takeda
	4	11/01/82	Kukiko No. 1	Wister	Female		S → C	E Wing	Takeda
	5	11/01/82	Kukiko No. 2	Wister	Female		S → C	E Wing	Takeda
	6	11/01/82	Kukiko No. 3	Wister	Female		S → C	E Wing	Takeda
	7	2/2/83	ME (R) A-♂-72	Fischer	Male		SPF	B201	Matsuura
	8	2/2/83	ME (R) B-♂-72	Fischer	Male		SPF	B201	Matsuura
	9	2/2/83	ME (R) C-♂-72	Fischer	Male		SPF	B201	Matsuura
	10	2/2/83	ME (R) D-♂-72	Fischer	Male		SPF	B201	Matsuura
	11	2/2/83	ME (R) E-♂-24	Fischer	Male		SPF	B201	Matsuura
	12	2/2/83	ME (R) A-♀-71	Fischer	Female		SPF	B201	Matsuura
	13	2/2/83	ME (R) B-♀-72	Fischer	Female		SPF	B201	Matsuura
	14	2/2/83	ME (R) C-♀-72	Fischer	Female		SPF	B201	Matsuura
	15	2/2/83	ME (R) D-♀-72	Fischer	Female		SPF	B201	Matsuura
	16	2/2/83	ME (R) E-♀-24	Fischer	Female		SPF	B201	Matsuura

Governmental Commission Methanol	ME 58
--	--------------

Results of Infection Tests on Mice and Rats (Serological Reaction) Animal Care Facility: Mitsubishi Kasei Institute of Toxicology and Environmental Sciences, Ltd

Test Date: July 13, 1983 Test No. D-89

[seal: Takeda, 7/18/1983, (Kazu)]

Microorganism \ Animal	F344 42W A72, M	A 72, F	B72, M	B72, F	C72, M	C72, F	D72, M	D72, F	E23, M	E24, F
<i>Corynebacterium kutscheri</i>	— *	—	—	—	—	—	—	—	—	—
<i>Salmonella typhimurium</i>	—	—	—	—	—	—	—	—	—	—
<i>Tyzzer's organism</i>	—	—	—	—	—	—	—	—	—	—
<i>Myeoplasma pulmonis</i>	—	—	—	—	—	—	—	—	—	—
<i>Ectromelia virus</i>										
<i>Mouse adenovirus</i>	—	—	—	—	—	—	—	—	—	—
<i>Mouse hepatitis virus</i>	—	—	—	—	—	—	—	—	—	—
<i>Sendai virus</i>	—	—	—	—	—	—	—	—	—	—
	* Antibody titer < 1:10 (negative)									

Test No. 2: Blood sampling on June 23, 1983 (9 months into the study)

[seal: Seal of ICLAS Monitoring Center, Central Institute for Experimental Animals]

ICLAS Monitoring Center, Central Institute for Experimental Animals

1430 Nogawa, ~~Takatsu~~ Miyamae-ku, Kawasaki-shi, 213, TEL (044) 751-2084 (direct)

Mgr	Tester
[seal: Kagiyama]	[seal: Ito]

Governmental Commission Methanol	ME 58
--	--------------

[seal: Takeda, 10/31/1983, (Kazu)]

Results of Infection Tests on Mice and Rats (Serological Reaction)

Animal Care Facility: Mitsubishi Kasei Institute of Toxicology and

Environmental Sciences, Ltd Test Date: Oct. 26, 1983 Test No. D-210

Microorganism \ Animal	F344 50W, M A-72	B-72	C-72	D-71	E-24	50W, F A-72	B-72	C-72	D-71	E-24
<i>Corynebacterium kutscheri</i>	— *	—	—	—	—	—	—	—	—	—
<i>Salmonella typhimurium</i>	—	—	—	—	—	—	—	—	—	—
<i>Tyzzer's organism</i>	—	—	—	—	—	—	—	—	—	—
<i>Myeoplasma pulmonis</i>	—	—	—	—	—	—	—	—	—	—
<i>Ectromelia virus</i>										
<i>Mouse adenovirus</i>	—	—	—	—	—	—	—	—	—	—
<i>Mouse hepatitis virus</i>	—	—	—	—	—	—	—	—	—	—
<i>Sendai virus</i>	—	—	—	—	—	—	—	—	—	—
	* Antibody titer < 1:10 (negative)									

Test No. 3: Blood sampling on September 5, 1983 (12 months into the study)

[seal: Seal of ICLAS Monitoring Center, Central Institute for Experimental Animals]

ICLAS Monitoring Center, Central Institute for Experimental Animals1430 Nogawa, ~~Takatsu~~ Miyamae-ku, Kawasaki-shi, 213, TEL (044) 751-2084 (direct)

Mgr	Tester
[seal: Kagiya]	[seal: Ito]

Governmental Commission Methanol	ME 58
--	----------

[seal: Takeda, 2/[illegible]/1984, (Kazu)]

Request No.

Results of Infection Tests on Mice and Rats (Serological Reaction) Animal Care Facility: Mitsubishi Kasei Institute of Toxicology and Environmental Sciences, Ltd

Test Date: Jan. 25, 1984 Test No. D-313

Microorganism \ Animal	F344 70W, M A-51	B-52	C-52	D-52	E-14	70W, F A-52	B-52	C-52	D-52	E-15
<i>Corynebacterium kutscheri</i>	— *	—	—	—	—	—	—	—	—	—
<i>Salmonella typhimurium</i>	—	—	—	—	—	—	—	—	—	—
<i>Tyzzer's organism</i>	—	—	—	—	—	—	—	—	—	—
<i>Myeoplasma pulmonis</i>	—	—	—	—	—	—	—	—	—	—
<i>Ectromelia virus</i>										
<i>Mouse adenovirus</i>	—	—	—	—	—	—	—	—	—	—
<i>Mouse hepatitis virus</i>	—	—	—	—	—	—	—	—	—	—
<i>Sendai virus</i>	—	—	—	—	—	—	—	—	—	—
	* Antibody titer < 1:10 (negative)									

Test No. 4: Blood sampling on January 19, 1984 (16 months into the study)

[seal: Seal of ICLAS Monitoring Center, Central Institute for Experimental Animals]

ICLAS Monitoring Center, Central Institute for Experimental Animals

1430 Nogawa, Miyamae-ku, Kawasaki-shi, 213, TEL (044) 751-2084 (direct)

Mgr	Tester
[seal: Kagiyama]	[seal: Ito]

Governmental Commission Methanol	ME 59
--	--------------

Request No.

Results of Infection Tests on Mice and Rats (Serological Reaction) Animal Care Facility: Mitsubishi Kasei Institute of Toxicology and Environmental Sciences, Ltd

Test Date: May 23, 1984 Test No. D-495

Microorganism	Animal	F344 87W, M A-51	B-52	C-52	D-52	E-13	87W, F A-52	B-52	C-52	D-52	E-15
<i>Corynebacterium kutscheri</i>		— *	—	—	—	—	—	—	—	—	—
<i>Salmonella typhimurium</i>		—	—	—	—	—	—	—	—	—	—
<i>Tyzzer's organism</i>		—	—	—	—	—	—	—	—	—	—
<i>Myeoplasma pulmonis</i>		—	—	—	—	—	—	—	—	—	—
<i>Ectromelia virus</i>											
<i>Mouse adenovirus</i>		—	—	—	—	—	—	—	—	—	—
<i>Mouse hepatitis virus</i>		—	—	—	—	—	—	—	—	—	—
<i>Sendai virus</i>		—	—	—	—	—	—	—	—	—	—
		* Antibody titer < 1:10 (negative)									

Test No. 5: Blood sampling on May 17, 1984 (20 months into the study)

[seal: Seal of ICLAS Monitoring Center, Central Institute for Experimental Animals]

ICLAS Monitoring Center, Central Institute for Experimental Animals

1430 Nogawa, Miyamae-ku, Kawasaki-shi, 213, TEL (044) 751-2084 (direct)

Mgr	Tester
[seal: Kagiyama]	[seal: Ito]

--	--

Request No.

Results of Infection Tests on Mice and Rats (Serological Reaction)

Animal Care Facility: Mitsubishi Kasei Institute of Toxicology and Environmental Sciences, Ltd

Test Date: Dec. 19, 1984 Test No. D-794

Microorganism \ Animal	F344 104W, M A-1	B-2	C-2	D-1	E-2	104W, F A-1	B-1	C-1	D-1	E-1
<i>Corynebacterium kutscheri</i>	—	—	—	—	—	—	—	—	—	—
<i>Salmonella typhimurium</i>	—	—	—	—	—	—	—	—	—	—
<i>Tyzzer's organism</i>	—	—	—	—	—	—	—	—	—	—
<i>Myeoplasma pulmonis</i>	—	—	—	—	—	—	—	—	—	—
<i>Ectromelia virus</i>										
<i>Mouse adenovirus</i>	—	—	—	—	—	—	—	—	—	—
<i>Mouse hepatitis virus</i>	—	—	—	—	—	—	—	—	—	—
<i>Sendai virus</i>	—	—	—	—	—	—	—	—	—	—

Note) Antibody titer of more than 10X is positive.

[seal: Seal of ICLAS Monitoring Center, Central Institute for Experimental Animals]

ICLAS Monitoring Center, Central Institute for Experimental Animals

1430 Nogawa, Miyamae-ku, Kawasaki-shi, 213, TEL (044) 751-2084 (direct)

Mgr	Tester
[seal: Kagiyama]	[seal: Ito]

Test No. 6: Blood sampling on September 18 (male) and September 25 (female), 1984
(24 months into the study)